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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,812	LIN, BIAOYANG	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-33* is/are pending in the application.

4a) Of the above claim(s) *17-23 and 27-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group XII, claims 24-26 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that 1) Regarding polypeptide claims and related methods, groups XIV and XV should be rejoined with the elected group XII, because a thorough search for the elected claims would likely uncover any art relevant to the methods of groups XIV and XV, and thus it would not be a serious burden for the Examiner to search all these groups together. For analogous reasons, the composition claims of group XX should be rejoined with the method claims of groups XXII and XXIII, and the composition claims of group XXVIII should be rejoined with the method claims of groups XXX and XXXI, 2) Regarding polynucleotide claims and related methods, for analogous reasons set forth, the composition claims of group I should be rejoined with the method claims of groups II and III, the composition claims of group V should be rejoined with the method claims of groups VI and VII, the composition claims of group IX should be rejoined with the method claims of groups X and XI, the composition claims of group XVII should be rejoined with the method claims of groups XVIII and XIX, the composition claims of group XXV should be rejoined with the method claims of groups XXVI and XXVII, 3) Regarding methods of diagnosis and methods of predicting susceptibility, each pair of groups shares the same method steps and is classified in the same class and subclass, wherein similar search would be done for each pair of groups, and it would not be a serious burden for the Examiner to search all these groups together, and 4) Regarding species election, a thorough search for the elected species would likely uncover any art relevant to the other species. This is not found persuasive

because of the following reasons: 1) The composition claims are different from the method claims as product and process. Further, the scope of the methods are different from that of the composition claims, and the searches for the methods and composition claims are not co-extensive and it would be a burden for the Examiner to search the different groups together, 2) Regarding methods of diagnosis and methods of predicting susceptibility, a person who is predicted to be susceptible to prostate cancer does not necessarily develop prostate cancer. Thus the scope of the two different methods are different, and the searches for the two methods are not-coextensive. Further, the searches for the two groups are based on several databases and are not based solely on classification search, and 3) Different species have different characteristic and properties, and the search for different species are not co-extensive and it would be a burden for the Examiner to search the different species together.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 24-26 are examined in the instant application.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement of 06/25/02 could not be examined because although the form 1449 was submitted, the references are missing.

Claim Rejections - 35 USC § 112, SECOND PARAGRAPH

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-26 are indefinite for the use of the language "substiantially pure".in claims 24-26 The term "substiantially pure" in claims 24-26 is a relative term which renders the claim indefinite. The specification defines a "substantially pure nucleic acid molecule" as a nucleic acid molecule that is "substantially free" from cellular components or other contaminants that are not the desired molecule (p.16, lines 18-21). It is noted that the term "substantially pure nucleic acid molecule" is not defined. However, even if the definition for "substantially pure nucleic acid molecule" were to be applied to the present claims, since the term "substantially free" is not defined by the specification, and since a definition of "substantially pure" depends on a relative, non-defined term "substantially free", the term "substantially pure" is also a relative term. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 101, UTILITY

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement

thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 24-26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 24-26 are drawn to an ARP3 polypeptide, comprising an amino acid sequence having at least 45% identity with SEQ ID NO:5, or the amino acid sequence of SEQ ID NO:5, and an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5.

It is noted that an ARP3 polypeptide, comprising "an amino acid sequence" having at least "45% identity" with SEQ ID NO:5 encompasses variants of SEQ ID NO:5.

The specification discloses that the ARP3 polypeptide of SEQ ID NO:5 is a predicted polypeptide encoded by SEQ ID NO:4 (p.74, lines 21-22 and figure 3)), wherein SEQ ID NO: 4 is isolated from mRNAs of prostate carcinoma cell line LNCaP in the presence or absence of androgen (p.71, last paragraph bridging p.72). The specification further contemplates making antibodies specific for SEQ ID NO:5 (p. 30), diagnozing or predicting susceptibility to prostate cancer, wherein altered expression of ARP3 as compared to the control expression level is an indication of prostate neoplastic conditions (page 36, second paragraph), and the use of the claimed ARP3 polypeptide as a vaccine or of ARP3 regulatory agents for treating prostate cancer (p.62, last paragraph to p.64).

It is noted that there is no data however showing that the polynucleotide of SEQ ID NO:4 or the predicted encoded polypeptide of SEQ ID NO:5 and its variants are overexpressed in prostate cancer tissues as compared to normal prostate tissues, or that the polynucleotide of SEQ ID NO:4 or the predicted encoded polypeptide of SEQ ID NO:5 and its variants are detected outside of the prostate tissue.

The utility for the polypeptide of SEQ ID NO:5 is questionable, because one cannot predict that SEQ ID NO:5 and its variants actually exists in nature, and is expressed in a prostate-specific manner. Although the polynucleotide of SEQ ID NO:4 is expressed in a prostate tumor cell line LNCaP, and is androgen regulated, it is however unpredictable that the protein of SEQ ID NO:5 and its variants actually exist in nature, due to possible translation and post-translational negative control. It is well known in the art that regulation of mRNA translation is one of the major regulatory steps in the control of gene expression (Jansen, M et al, 1995, Pediatric Res, 37 (6): 681-686). Further, those of skill in the art recognize that expression of mRNA, specific for a tissue type, does not dictate nor predict the translation of such mRNA into a polypeptide. For example, Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) teach that translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Many other proteins are regulated at the translational level rather than the transcriptional level. For instance, Shantz and Pegg (Int J of Biochem and Cell Biol., 1999, Vol. 31, pp. 107-122) teach that ornithine decarboxylase is highly regulated in the cell at the level of

translation and that translation of ornithine decarboxylase mRNA is dependent on the secondary structure of the mRNA and the availability of eIF-4E, which mediates translation initiation. McClean and Hill (Eur J of Cancer, 1993, vol. 29A, pp. 2243-2248) teach that p-glycoprotein can be overexpressed in CHO cells following exposure to radiation, without any concomitant overexpression of the p-glycoprotein mRNA. In addition, Fu et al (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Yokota, J et al (Oncogene, 1988,Vol.3, pp. 471-475) teach that the retinoblasma (RB) 115 kD protein is not detected in all nine cases of lung small-cell carcinoma, with either normal or abnormal size mRNA, whereas the RB protein is detected in three of four adenocarcinomas and all three squamous cell carcinomas and one of two large cell carcinomas expressing normal size RB mRNA. Thus, predictability of protein translation or the extent of translation is not solely contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. For the above reasons, one of skill in the art would not be able to predict if SEQ ID NO:4 is translated into a polypeptide expression product, or even if translated, whether it is overexpressed as compared to normal control.

Further, even if the polynucleotide of SEQ ID NO:4 is translated into the polypeptide of SEQ ID NO:5 in nature, it is unpredictable that SEQ ID NO:4, SEQ ID NO:5 and its variants actually exist in nature in prostate tumor tissues, and is overexpressed in a prostate-specific manner, because SEQ ID NO:4 is obtained from

the prostate tumor cell line LNCaP, which does not have the same characteristics or properties of prostate cancer tissue. It is well known in the art that characteristics of cultured cell lines generally differ significantly from the characteristics of a primary tumor. Drexler et al (Leukemia and Lymphoma, 1993, 9:1-25) specifically teach, in the study of Hodgkin and Reed-Sternberg cancer cells in culture, that the acquisition or loss of certain properties during adaptation to culture systems cannot be excluded and that only a few cell lines containing cells that resemble the *in-vivo* cancer cells have been established and even for the *bona fide* cancer cell lines it is difficult to prove that the immortalized cells originated from a specific cancer cell (see attached abstract). Further, Embleton et al (Immunol Ser, 1984, 23:181-207) specifically teaches that in procedures for the diagnosis of osteogenic sarcoma, caution must be used when interpreting results obtained with monoclonal antibodies that had been raised to cultured cell lines and specifically teach that cultured tumor cells may not be antigenically typical of the tumor cell population from which they were derived and it is well established that new artifactural antigens can occur as a result of culture (see attached abstract). Hsu (in Tissue Culture Methods and Applications, Kruse and Patterson, Eds, 1973, Academic Press, NY, see abstract, p.764) specifically teaches that it is well known that cell cultures *in vitro* frequently change their chromosomal constitutions (see abstract). Mustafa O et al, 1996, Intl J Oncology, 8(5): 883-888, teach that prostate cells in late culture all show numerous changes in chromosome 5 in addition to some new markers. The evidence presented clearly demonstrates that in cell culture systems, in general, and in cancer derived cell lines in particular, that artifactural chromosome constitutions

and antigen expression are expected and must be taken into account when interpreting data received from cell line assays. Further, Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences *In Vitro*). Further, Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Further, Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary -type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not, yet normal or malignant cells *in vivo* are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those *in vivo* and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell

interations. Thus, based on the cell culture data presented in the specification, it could not be predicted that the polynucleotide of SEQ ID NO:4 and its predicted, encoded polypeptide of SEQ ID NO:5 actually exist in nature in prostate tumor tissues, in a prostate-specific manner and are overexpressed as compared to normal control.

In addition, even if the claimed polypeptide of SEQ ID NO:5 is expressed in a prostate-specific manner, this prostate specificity would not constitute a specific utility, because said utility is shared by several other prostate specific polypeptides.

Further, the utility for the polypeptide of SEQ ID NO:5 and its variants is questionable, because neither the specification nor any art of record teaches what the polypeptide SEQ ID NO: 5 is, what it does do. They do not teach a utility for any of the fragments claimed; they do not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases. The asserted utilities for SEQ ID No: 5, such as production of antibodies apply to many unrelated polypeptide structures sequences. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to SEQ ID NO: 5.

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for SEQ ID NO: 5. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Claims 24, 26 are drawn to an ARP3 polypeptide, comprising "an amino acid sequence" having at least 45% identity with SEQ ID NO:5, and an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5.

It is noted that an ARP3 polypeptide, comprising an amino acid sequence having at least "45% identity" with SEQ ID NO:5 encompasses variants of SEQ ID NO:5.

It is also noted that "an" amino acid sequence encompasses a two amino acid sequence or a two amino acid fragment of SEQ ID NO:5. Thus claim 24 encompasses unrelated sequences that share with SEQ ID NO:5 two amino acids.

It is further noted that an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5 encompasses unrelated sequences that share with SEQ ID NO:5 eight contiguous amino acids.

Although drawn specifically to the DNA art, the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly relevant to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The specification discloses polypeptide variants of SEQ ID NO:5, which are naturally occurred or could be obtained by mutation using recombinant techniques (p.24-25)

The claims 24, 26 however read on variants of SEQ ID NO:5 , wherein said variants have any type of substitution besides conservative substitution, at any amino acid, throughout the length of the polypeptide, as well as insertions and deletions. The specification and the claims do not place any limit on which amino acid to be subjected to conservative or non-conservative substitution, the type of substitution besides conservative substitution, nor the type of amino acids replacing the original amino acids. In addition, the specification and all other pending claims do not place any limit on the number of amino acids that could be substituted. Although the specification discloses that the types of changes are routinely done in the art, the specification and the claims do not provide any guidance as to which, or how many original amino acid(s) to be substituted, or to which type of substitution besides conservative substitution, or which amino acids could be deleted or inserted so that the claimed polypeptide could function as contemplated. Structural features, that could distinguish the claimed variants from the polypeptide sequences known in the art are missing from the disclosure. No common structural attributes that identify the claimed variants are disclosed. In addition, no common functional attributes that identify the claimed variants are disclosed, because the function of a sequence could be abolished, even with substitution of only one amino acid of the polypeptide (Burgess et al. Journal of Cell Biology, 1990, 11: 2129-2138). The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed variants, SEQ ID NO: 5 alone is insufficient to describe said

variants. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of variants. Thus, applicant was not in possession of the claimed variants.

Thus, there is insufficient support of claims 24, 26 as provided by the Interim Written Description Guidelines published in the June 5, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH, ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph.

Claims 24-26 are drawn to an ARP3 polypeptide, comprising "an amino acid sequence" having at least 45% identity with SEQ ID NO:5 (claim 24), or the amino acid sequence of SEQ ID NO:5 (claim 25), and an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5 (claim 26).

Specifically, since the claimed invention is not supported by a well established utility for the reasons set forth in the rejection under 35 USC 101 above, one skilled in the art clearly would not know how to make/use the claimed invention.

Claim R jections - 35 USC § 112, FIRST PARAGRAPH, SCOPE

If Applicant could overcome the above 101 and 112, first paragraph rejections, claims 24, 26 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5, does not reasonably provide enablement for variants of SEQ ID NO:5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 24, 26 are drawn to an ARP3 polypeptide, comprising "an amino acid sequence" having at least 45% identity with SEQ ID NO:5 (claim 24), and an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5 (claim 26).

Claims 24, 26 encompasses variants of SEQ ID NO:5.

Applicant not shown that variants of SEQ ID NO: 5 are capable of functioning as that which is being disclosed.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein (Burgess et al. Journal of Cell Biology, 1990, 11: 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cell Biology, 1988, 8: 1247-1252). Similarly, it

has been shown that aglycosylation of antibodies reduces the resistance of the antibodies to proteolytic degradation, while CH2 deletions increase the binding affinity of the antibodies (see Tao. et al. The Journal of Immunology, 1989, 143(8): 2595-2601, and Gillies et al. Human Antibodies and Hybridomas, 1990, 1(1): 47-54). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein.

In view of the above unpredictability, one of skill in the art would be forced into undue experimentation in order to perform the claimed invention as broadly as claimed.

In addition, although conservative subsititution would not destroy the biological function of a protein, the specification fails to disclose which amino acid(s) would be subjected to conservative substitution. In the absence of a source of method of making such variants, one of skill in the art would be forced into undue experimentation to practice the claimed invention as broadly as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 24, 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Rosen, CA et al, Genbank Sequence Database (Accession No: AAB53386), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available on September 2000.

Claims 24, 26 are drawn to an ARP3 polypeptide, comprising "an amino acid sequence" having at least 45% identity with SEQ ID NO:5, and an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5.

Rosen et al teach a sequence which is 100% similar to the claimed SEQ ID NO:5, from amino acid 372 to 537, under MPSRCH sequence homology search (MPSRCH search report, 2002, us-09-821-812-5.rag, page 2).

Given the polypeptide sequence taught by Rosen et al, one of ordinary skill in the art would immediately envision the claimed polypeptide or fragments thereof.

2. Claims 24, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Emerson SU et al, Genbank Sequence Database (Accession No: AAW93405), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available on January,1999.

Claims 24, 26 are drawn to an ARP3 polypeptide, comprising "an amino acid sequence" having at least 45% identity with SEQ ID NO:5, and an ARP3 polypeptide fragments "comprising" at least eight contiguous amino acids of SEQ ID NO:5.

Emerson et al teach a sequence which is 100% similar to the claimed SEQ ID NO:5 from amino acid 327 to 334, under MPSRCH sequence homology search (MPSRCH search report, 2002, us-09-821-812-5.rag, page 5).

Given the polypeptide sequence taught by Emerson et al, one of ordinary skill in the art would immediately envision the claimed polypeptide or fragments thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

August 13, 2002